

*Alleged claim rejections under 35 U.S.C. § 112, second paragraph*

Claims 32-38, 42, 56, 57, 59, 60, and 70 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants have revised Claims 32 and 42 to obviate this rejection.

*Alleged claim rejections under 35 U.S.C. § 112, first paragraph*

Claims 23-31, 54, 55, 63, and 69 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing “new matter”. Applicants have revised Claim 23 to correct a clerical error that apparently led to the instant rejection. Accordingly, this rejection may be properly withdrawn.

Claims 6-38, 42, 49, 50, 52-63, and 67-70 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an enabling description. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of non-enablement is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

Applicants respectfully point out the well established standard that an application must be taken as presumptively enabling unless there is objective reason to doubt the statements contained therein (see MPEP 2164.04 and the case decisions cited therein, such as *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). This presumption is present before any “determination of enablement” is to occur under the *In re Wands* factors as cited in the instant rejection. Applicants submit that no objective reason has been provided to doubt the presumption of enablement in the pending claims.

None of the cited documents relates to the use of HoxB13 and IL17BR gene expression in relation to breast cancer. Accordingly, no objective reasons have been provided to

support the instant rejection. Instead, the rejection is based on multiple unsupported statements that appear to be subjective in nature and that clearly contravene the **presumption** of enablement required by *Marzocchi*. Applicants respectfully point out that the assertion that even Claims 67-70 are not enabled is evidence of the non-objective nature of the instant rejection.

Accordingly, no *prima facie* case of non-enablement is present, and the instant rejection may be properly withdrawn.

Claims 6-38, 42, 49, 50, 52-63, and 67-70 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an adequate written description. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of an inadequate written description is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

The basis of this rejection appears to be that an actual reduction to practice of the invention is necessary to satisfy the written description requirement. Applicants point out, however, that U.S. patent law does **not** require actual reduction to practice.

Therefore, no *prima facie* case is present, and this rejection may be properly withdrawn.

*Alleged provisional rejections based on nonstatutory obviousness-type double patenting*

Claims 6-22, 32-38, 42, 49, 50, 52, 53, 56-62, 67, 68, and 70 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 1, 2, 4-20, 29-39 and 41-43 of U.S. Patent 7,504,214 B2.

Claims 6, 7, 9-15, 17-22, 32, 34-38, 42, and 58-62 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 1 and 9-27 of co-pending application no. 11/089,097.

Applicants respectfully request that the requirement for Terminal Disclaimers be held in abeyance until the pending claims are otherwise held allowable.

Claims 6, 7, 9-15, 17-22, 32, 34-38, 42, and 58-62 have been alleged to be “not patentably distinct” from Claims 1 and 9-27 in co-pending application no. 11/089,097.

Applicants will consider additional showings in due course.

### **CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 425-681-1833.

Respectfully submitted,

/kawai lau/  
Kawai Lau, Ph.D.  
Reg. No. 44,461

PATENTIQUE PLLC  
PO Box 5803  
Bellevue, Washington 98006  
Tel: 425-228-0818  
Fax: 425-228-8192